

Notice of Allowability

Application No.

09/888,072

Examiner

Anand U Desai, Ph.D.

Applicant(s)

GREENWALD ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.
2. ☒ The allowed claim(s) is/are 1,5,9,11,15-17 and 19-26.
3. ☒ The drawings filed on 22 June 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20040723</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

1. This office action is in response to amendment filed on April 30, 2004. New claims 17-26 have been added. Claims 1, 5, 9, 11, 15-26 are currently pending and are under examination.

EXAMINER'S AMENDMENT

2. An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

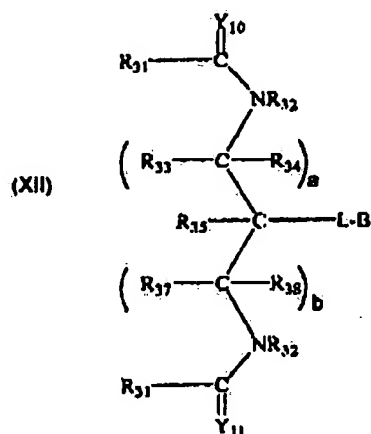
Authorization for this examiner's amendment was given in a telephone interview with Mr. Michael N. Mercanti on July 23, 2004.

Examiner's Amendment to the Claims:

2. (Cancelled).
3. (Cancelled).
4. (Cancelled).
6. (Cancelled).
7. (Cancelled).
8. (Cancelled).
10. (Cancelled).
12. (Cancelled).
13. (Cancelled).
14. (Cancelled).

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15. (Currently amended) A method of preparing a polymeric conjugate, comprising reacting a compound of formula (XII)



wherein

R_{31} is a linear or branched polymer residue;

Y_{10} and Y_{11} are independently O, S, or NR_{40} ;

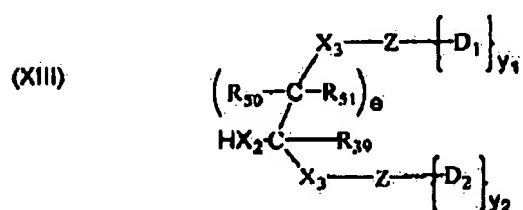
L is an amino acid residue or a bifunctional linker;

R_{32} , R_{33} , R_{34} , R_{35} , R_{37} , R_{38} , and R_{40} are independently selected from the group consisting of hydrogen, C_{1-6} alkyls, C_{3-12} branched alkyls, C_{3-8} cycloalkyls, C_{1-6} substituted alkyls, C_{3-8} substituted cycloalkyls, aryls, substituted aryls, aralkyls, C_{1-6} heteroalkyls and substituted C_{1-6} heteroalkyls;

a and b are each independently a positive integer, and

B is a leaving group;

with a compound of the formula (XIII)

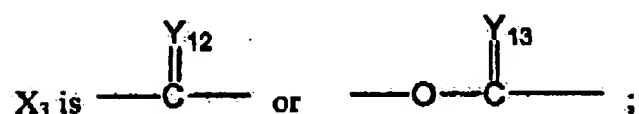


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wherein

 X_2 is O, S, or NR_{41} ;

R_{39} , R_{41} , R_{50} and R_{51} are independently selected from the group consisting of hydrogen, C_{1-6} alkyls, C_{3-12} branched alkyls, C_{3-8} cycloalkyls, C_{1-6} substituted alkyls, C_{3-8} substituted cycloalkyls, aryls, substituted aryls, aralkyls, C_{1-6} heteroalkyls and substituted C_{1-6} heteroalkyls;

wherein Y_{12} and Y_{13} are independently O, S, or NR_{41} ;

Z is selected from the group consisting of a bond, a moiety that is actively transported into a target cell, a hydrophobic moiety, and combinations thereof;

D_1 and D_2 are independently selected from the group consisting of OH, a residue of a hydroxyl, a residue of an amine-containing moiety and a leaving group;

 e is a positive integer; and y_1 and y_2 are independently selected positive integers;

under conditions sufficient to cause a substitution reaction in which the compound of formula (X) is formed, and isolating the polymer conjugate of formula (X).

18. (Cancelled).

24. (Currently amended) The compound of claim 1, wherein R_{32} - R_{35} , R_{37} - R_{40} , R_{50} , and R_{51} are each hydrogen.

Claim Rejections - 35 USC § 112

3. Upon review of Applicant's amendment there are no outstanding 35 U.S.C § 112 rejections.

Claim Rejections - 35 USC § 103

4. Upon review of Applicant's amendment the 35 U.S.C. § 103 rejection of claims 1, 5, 9, 11, 15, and 16 are withdrawn.

Allowable Subject Matter

5. Claims 1, 5, 9, 11, 15-17, and 19-26 are allowable.
6. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

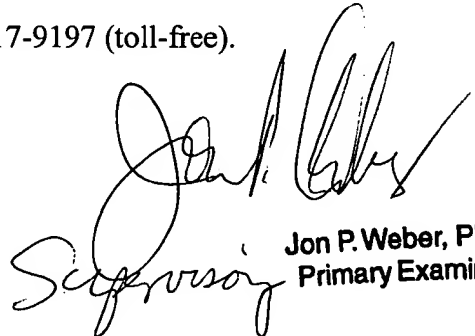
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

July 23, 2004

A handwritten signature in black ink, appearing to be 'AD' or similar, located below the date.A large, stylized handwritten signature in black ink, likely belonging to Jon P. Weber, located to the left of his printed name.

Jon P. Weber, Ph.D.
Primary Examiner